

OFFICE OF SPECIAL PROGRAMS

FY 2001 Performance Plan, Revised Final FY 2000 Plan and FY1999 Performance Report

The Office of Special Programs (OSP) in HRSA is responsible for two program activities in the Division of Transplantation involving the transplantation of organs, tissues, and bone marrow to treat those with life threatening diseases.

The total number of organ transplants increased 60% between 1988 and 1998, but the number of transplant candidates is rising faster than the number of donors. 1998 data show 5,799 donors, up from 5,477 the year before. This is not enough of an increase to keep pace with the need for organs. 1999 data show 66,983 registrants waiting for organs, representing a 10% increase from 1998, and the gap between supply and demand for organs continued to widen. Between 1995 and 1997, the median waiting times for all organs increased. There were 4,327 reported deaths on the waiting list in 1997, up from 1,484 deaths reported in 1988. Furthermore, the number of people on the waiting list is increasing much faster than the number of transplants. Every year the need for organ donation is greater.

The HRSA OSP transplantation programs are authorized by the National Organ Transplant Act of 1984, as amended; and the National Bone Marrow Registry Reauthorization Act of 1998. Taken together, these programs reflect the HRSA/OSP's major strategic organ/tissue and marrow transplantation goals of increasing the numbers of organ donors nationally, increasing the number of minority organ donors nationally, increasing the number of unrelated patients receiving marrow transplants nationally, increasing the number of unrelated marrow donors nationally, increasing the number of minority patients receiving marrow transplants nationally, and increasing the number of unrelated minority donors nationally.

Programs included in this section are:

- 2.24 Organ Procurement and Transplantation
- 2.25 National Bone Marrow Donor Program

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2.24 Program Title: Organ Procurement and Transplantation

Performance Goals	Targets	Actual Performance	Reference
I. ELIMINATE BARRIERS TO CARE C. Focus on Target Population 1. Increase by 20% over two years the number of organ donors nationally from implementation of the final HCFA Rule on Conditions of Participation of Hospitals. (Sept. 98)	FY 01: 7,248 donors FY 00: 6,589 FY 99: 5,990	FY 01: FY 00: FY 99: (5/00) FY 98: 5,799 FY 97: 5,477 donors	B225
II. ELIMINATE HEALTH DISPARITIES B. Increase Utilization for Underserved Populations 1. Increase by 20% over two years the number of minority organ donors nationally from implementation of the final HCFA Rule on Conditions of Participation of Hospitals.	FY 01: 1,802 donors FY 00: 1,638 FY 99: 1,489	FY 01: FY 00: FY 99: (5/00) FY 98: 1,378 FY 97: 1,342 donors	B225
Total Funding: Organ Procurement and Transplantation (\$ in 000's)	FY 2001: \$15,000 FY 2000: \$10,000 FY 1999: \$ 9,997 FY 1998: \$ 2,778	B x: page # budget HP: Healthy People goal	

2.24.1 Program Description, Context and Summary of Performance

The HRSA/Office of Special Program (OSP) organ procurement and transplantation programs are

authorized by the National Organ Transplant Act of 1984, as amended. The Division of Transplantation's (DoT) principal responsibilities include the management of the Organ Procurement and Transplantation Network (OPTN), Scientific Registry of Transplant Recipients (SRTR), National Marrow Donor Program (NMDP) contracts, public and professional education, technical assistance to organ procurement organizations (OPO's), administration of the "Model Interventions to Increase Organ and Tissue Donation" grant program. For organ procurement and transplantation data, OSP/DoT is dependent upon the United Network for Organ Sharing (UNOS) which hold the Federal OPTN and SRTR contracts. UNOS continually updates this data and publishes an annual report of transplantation activities. The 1999 Annual report contains data from 1989 to 1998 inclusive; it should be noted that 1999 data are not available.

DoT's activities support the National Organ and Tissue Donation Initiative (the National Initiative), launched in December 1997 by Vice President Al Gore and HHS Secretary Donna Shalala. The intent of the National Initiative is to increase the number of organ donors by 20% over two years beginning with the implementation of HCFA's Hospital Conditions of Participation (COP) for Organ, Tissue, and Eye Donation in August 1998. Working with HHS, HRSA/OSP/DoT is partnering with an array of organizations across the U.S., building on more than a decade of experience gained from government, private, and volunteer efforts. DoT's goals and performance measures reflect the three major goals of the National Initiative.

- *Increasing consent to donation
- *Ensuring that families are asked about donation
- *Learning more about what works to increase donation

The first goal can be viewed from two perspectives: 1) family consent at the time of request for the donation of a loved one's organs in the hospital setting; and 2) individual declaration of intent to donate via an advance directive, e.g., donor card or driver's license. DoT is addressing family consent through increasing awareness about organ and tissue donation, assessing the potential donor family's hospital experience, promoting family discussion about donation, and working with HCFA on implementation of the COP's requirement for training of designated requestors. Increasing individual declaration of intent is addressed through DoT programs encouraging people to sign donor cards or have donor indicators on driver's licenses, and critically, to follow these actions with a family discussion about the decision. A Gallup study has indicated that nearly all Americans would consent to donate their loved ones' organs if they knew beforehand that their loved ones wanted to donate. Programs in both family consent and individual intent are targeted to a variety of age and ethnic groups.

The second goal is intended to assure that families of all potential donors are given the opportunity to consent to donation. This is especially important because it has been suggested that improved trauma

care, seat belt and helmet law enforcement, and technical advancements in critical care medicine has contributed to the number of medically suitable potential donors holding constant, or even decreasing. A constant or decreasing number of suitable potential donors is a serious challenge to the achievement of a 20% increase in the number of donors in two years. Thus, it is imperative that all possible families are asked about donation. The COP contains a provision that all hospital deaths and imminent deaths are to be reported to the OPO serving the hospital. In this way, all potential donors can be identified and request procedures can be initiated. In addition, the actual donor pool may be increased through the adoption of expanded donor criteria. DoT supports public and professional education activities in these areas.

2. 24.2 Goal-by-Goal Presentation of Performance

Goal I.C.1: Increase by 20% over two years the number of organ donors nationally from implementation of the final HCFA Rule on Conditions of Participation of Hospitals (September, 1998).

Context:

This goal is consistent with the Department's National Initiative (described in 2.28.1 above). It is believed that implementation of the HCFA Rule will enable the goal to be met. Prior to the publication of the Rule, donation had been flat for several years. In the first partial year after publication, donation increased appreciably.

Indicator:

Number and percent change of organ donors nationally from implementation of the final HCFA Rule on Conditions of Participation of Hospitals.

Performance:

FY 1998 data show 5,799 donors, up from 5,477 the year before. This is an increase of 5.9%. During the same time period, the number of people waiting increased 13.5% from 53,505 to 60,712. From the end of 1998 until the end of 1999, the number of people waiting for organs increased from 60,712 to 66,983, or 10.3%. Although the rate of increase in the number of people waiting was slower in 1999, it continues to outpace the increase in cadaveric donation.

Goal II.B.1: Increase by 20% over two years the number of minority organ donors nationally from implementation of the final HCFA Rule on Conditions of Participation of Hospitals.

Context:

This goal is also consistent with the Department's National Initiative described above. Just as implementation of the HCFA Rule is expected to lead to a 20% increase in overall donation, it is expected to lead to a 20% increase in minority donation. Based on most recent data for 1998, it

appears that getting to 20% will be a greater challenge with minority donation than for overall donation. Expanded public information and education efforts may be required.

Indicator: Number and percent change of minority organ donors nationally from the effective date of the final HCFA Rule on Conditions of Participation of Hospitals.

Performance:

Trend Data:

1997:

651 Black donors

552 Hispanic donors

107 Asian donors

31 Other donors

1 Unknown donors in 1998 = 1,342 minority donors

1998:

654 Black donors

559 Hispanic donors

98 Asian donors

31 Other donors

1 Unknown donors in 1998 = 1,378 minority donors

FY 1999 Goal: 1,489 minority organ donors

FY 2000 Goal: 1,638 minority organ donors

FY 2001 Goal: 1,802 minority organ donors nationally

Data Collection and Validation

Data for performance goals were obtained from the following sources:

National Organ and Tissue Donation Initiative *Fact Sheet*

Medicine and Health, April 27, 1998, p. 3

HHS News Press Release, April 16, 1999

1998 Annual Report by UNOS, funded in part by HHS, pp.1, 2,15, and 32

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2.25 Program Title: National Bone Marrow Donor Program

Performance Goals	Targets	Actual Performance	Reference
I. ELIMINATE BARRIERS TO CARE C. Focus on Target Population 1. Increase by 7.5% the number of unrelated bone marrow donors (national registry of potential donors) over previous year totals.	FY 01: 4.35M donors FY 00: 4.04M FY 99: 2.84M	FY 01: FY 00: FY 99: 3.76 FY 98: 3.36 FY 96: 2.58 M donors	B227
II. ELIMINATE HEALTH DISPARITIES B. Increase Utilization for Underserved Populations 1. Increase by 10% the number of unrelated minority bone marrow donors (national registry of potential donors) over previous year totals.	FY 01: 1,100,000 donors FY 00: 1,000,000 FY 99: 220,000* *New donors. Total minority donors estimated at 900,000.	FY 01: FY 00: FY 99: (5/00) FY 98: 800,000 FY 96: 526,000 donors	B227
Total Funding: National Bone Marrow Donor Program (\$ in 000's)	FY 2001: \$ 17,959 FY 2000: \$ 18,000 FY 1999: \$ 17,994 FY 1998: \$ 15,270	B x: page # budget HP: Healthy People goal	

2.25. 1 Program Description, Context and Summary of Performance

Context:

The National Marrow Donor Program operates the national registry of volunteers willing to donate bone marrow to people with leukemia and other life threatening blood-based diseases who need a bone marrow transplant, but lack a relative with a matching tissue type. Through the program,

volunteer donors are recruited and tissue typed, the national registry of potential donors is maintained, computerized searches of the registry are conducted for patients, marrow is collected and provided for transplants maintained. The program provides information and case management for patients and their families, public and professional educational materials, and resources for transplant centers to conduct successful searches for unrelated matched donors. Research to improve the number and effectiveness of stem cell transplants using unrelated donors is conducted and supported by the program.

Program-level Performance:

Unrelated transplants are now performed using umbilical cord blood obtained at birth and peripheral blood stem cells derived through the process of apheresis, as well as bone marrow. There have also been many improvements in HLA-typing, moving toward more accurate DNA-based methods, and in procedures to reduce Graft-versus-Host disease (VHD). Currently, the NMDP Registry is made up of more than 3.7 million potential volunteer donors and the program has facilitated more than 9,000 transplants (over 1,300 in 1999). The NMDP's primary goal continues to be to provide the best possible source of hematopoietic stem cells from unrelated donors for patients who could not otherwise receive a transplant. Many diseases may be potentially cured with stem cell transplantation. As stem cell transplantation is more widely used as a therapy, and as evidence of its success as a therapy becomes more prevalent, it will likely be developed as an effective treatment for additional conditions.

2.25.2 Goal-by-Goal Presentation of Performance

Goal I.C.1: Increase by 7.5% the number of unrelated bone marrow donors (national registry of potential donors) over previous year totals.

Context:

The mission of the NMDP is to provide stem cells for transplants from compatible unrelated donors for patients from all racial and ethnic groups. In order for transplantation to succeed potential donors must match patients searching for a compatible donor. The likelihood of a potential donor matching a searching patient increases as the number of potential donors available on the Registry increases.

Indicator: Number and percent change of unrelated bone marrow donors (on the national registry).

Performance:

The number of potential donors has been increasing by at least 8% during the last three years but this increase is expected to level off as costs of registering potential donors increase.

Baseline: 2.58 million bone marrow donors in 1996

FY 99: 2.84

FY 2000 Goal: 4.04 million* (This is revised from the original target of 3.12 million donors based on the improved data base and a 7.5% increase).

FY 2001 Goal: 4.35 million bone marrow donors.

*** Revisions:**

Baseline is based on actual number of potential bone marrow donors on the national registry at the end of FY 96, rather than the end of calendar year 1996.

The FY 2000 goal is based on actual FY 99 performance of 3.76 million. This reflects the availability of more complete data on potential donor recruitment in recent years.

Goal II.B.1: Increase by 10% the number of unrelated minority bone marrow donors (national registry of potential donors) over previous year totals.

Context:

The mission of the NMDP is to provide stem cells for transplants from compatible unrelated donors for patients from all racial and ethnic groups. In order for transplantation to succeed potential donors must match patients searching for a compatible donor. The likelihood of a potential donor matching a searching patient increases as the number of potential donors of the same race/ethnicity on the registry increases. Statutory language notes that a primary function of the registry is to “increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group”.

Indicator: Number and percent change of unrelated minority bone marrow donors (national registry of potential donors) nationally.

Performance:

The number of potential donors has been increasing by at least 10% during the last three years, in part because of targeted recruitment efforts.

Baseline: 526,000 minority bone marrow donors on registry at end of 1996; increasing to 800,000 by end of FY 98.

FY 98. A cumulative total of 1,290 minority patients received stem cell transplants facilitated by the

national registry in FY 99, an increase of 21.13% over FY 98. The number of transplants is directly related to the ability to find a compatible donor who is available for transplant.

FY 99: 220,000 was the figure used to represent the minority bone marrow donors recruited to the registry in FY 99 instead of the total (900,000) potential minority bone marrow donors on registry at end of FY 99. The way the target was reported in FY 99 has been changed and is now being reported a different way for FY 2000 and FY 2001. This gives a better measurement of the performance goal.

FY 2000 Goal: 1.0 million* potential minority bone marrow donors on registry. 100,000 projected to be recruited in FY 2000.

FY 2001 Goal: 1.1 million potential minority bone marrow donors on registry.

* Revisions:

FY 2000 target is based on actual FY 99 performance. For recruitment of minority donors of unrelated bone marrow, the baseline and FY 2000 target have been substantially revised to reflect more complete data now available on potential donor recruitment in recent years which shows the effect of targeting minority donors.

Data Issues:

Data for performance goals were obtained from the National Marrow Donor Program. Data are provided to HRSA/Division of Transplantation monthly. The data are collected on a computerized system that contains information concerning potential donors, tissue typing results, potential recipients searching for a compatible donor, and transplant outcomes. These data are revised continuously as updated information becomes available. HRSA/DoT reviews reports and statistics as do the Board of Directors of the NMDP and the various NMDP committees.